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FEDERAL EXPRESS
Our Reference: 2915939

June 7, 2001

Dominic D. Corsaro and John A. Corsaro, Co-Owners C.B. Fresh Potato Products 25 "L" Street Fresno, CA 93721

# WARNING LETTER

Dear Mssrs. Corsaro and Corsaro:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 25 "L" Street, Fresno, California on May 3, 4, and 9, 2001.

The inspection revealed significant insanitary practices and conditions which cause your foods to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth.

As co-owners of your firm, you are responsible for ensuring that your facility has the proper construction and design and that your processes, controls, and procedures are adequate to store and process food under sanitary conditions.

The following is a list of the insanitary practices, conditions, and findings observed by FDA:

# 1. SANITARY OPERATIONS

- a. Pest Control: You are not taking effective measures to exclude pests from your plant, as evidenced by the following:
  - (1) A decomposed rat, approximately 10 inches long, was found near bags of sodium metabisulfite.
  - (2) Sixteen (16) rodent pellets, confirmed by FDA laboratory analysis, were found at various locations in the raw ingredients room.
  - (3) Six (6) decomposed mice were found near a pallet holding an opened box of food-packaging poly bags in your miscellaneous materials room (called junk room by the FDA investigator).

- (4) Approximately twenty (20) rodent pellets, eight of which were confirmed by FDA laboratory analysis, were found at the west side of the miscellaneous materials room.
- b. General Maintenance: You are not taking effective measures to maintain the building, fixtures, and other physical facilities of the plant in a sanitary condition, as evidenced by the following:
  - (1) Two live spiders were found in the northeast corner of the raw ingredient room, next to an uncovered wooden bin filled with raw potatoes.
  - (2) An uncovered wooden bin of raw potatoes and bagged raw ingredients were stored over wooden ceiling, piping, and lighting that were covered with dust-like debris and spider webbing in the raw ingredient room.
  - (3) Scraps of wood and empty cans, covered with dust-like debris and spider webbing, were piled against the walls on the south side of the raw ingredient room.
  - (4) Uncovered plastic bins of boiled potatoes were exposed to ceiling, walls, and flooring that had a buildup of brown-black mold-like material in the walk-in refrigerator.
  - (5) The metal casing around the light bulb suspended over bins of uncovered boiled potatoes bore a gray, crust-like material in the walk-in refrigerator.
  - (6) Uncovered plastic bins of cooled potatoes were exposed to moldy ceilings and walls in the shredding/dicing room.
  - (7) Three fans with dusty grills were blowing onto exposed raw potatoes as they were hauled up a conveyor belt in the processing room.
  - (8) There is a buildup of dried potato residue, dust, and debris along the peeled potato line in the processing room.
  - (9) The lighting unit directly above the hand-sorting table was covered with dust and spider-webs in the processing room.
  - (10)Two cigarette butts and spilled raw ingredients were found behind containers of raw ingredients in the processing room.

## 2. PLANT AND GROUNDS

# a. Plant Construction

Your plant is not constructed in such a manner that floors, walls, and ceiling may be adequately cleaned and kept clean and in good repair, as evidenced by the following:

- (1) The walls and ceiling in the shredding/dicing room bear a black mold-like substance.
- (2) The processing room floor is heavily pitted.
- (3) The south of the room, formerly known as the French-Fry Room, has missing concrete and the metal framing is exposed and bears rust-like debris.

#### b. Plant Design

The combination of activities that take place in the processing room increases the potential for contamination of food and food-contact surfaces. Specifically, the employees' microwave oven and coffee pot are next to the grill used to test browning

of hash browns; employees' food and drink items were found on the same table as the scale used to weigh finished product; and employees' shoes and a box of recycled cans were found directly underneath this table.

c. Placement of Equipment and Storage of Materials:

- (1) You do not provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations. Specifically, bins of uncovered raw potatoes, miscellaneous equipment, wooden shelving and pallets of raw ingredients were flush against the walls, preventing access to cleaning and maintaining rodent traps.
- (2) You do not take proper measures to ensure that drip or condensate from fixtures, ducts, and pipes does not contaminate food-contact surfaces. Specifically, the food shredder was stored beneath a refrigeration unit that was leaking condensation.

# 3. SANITARY FACILITIES AND CONTROLS

- a. Plumbing: You do not provide adequate floor drainage in areas where normal operations discharge water on the floor, as evidenced by the following:
  - (1) In the raw ingredient room, a five-gallon bucket filled with water and a floating cigarette butt was observed overflowing into the channel drain that leads to a drain underneath wooden bins used to store raw potatoes. The drain had 2" of standing dark-colored, sewage-smelling water. An employee identified the water as condensate from the freezer.
  - (2) In the processing room, there is a channel drain that contained rotten potato peels and up to 1" of standing dark-colored water.
  - (3) In the room, formerly known as the French-Fry Room, the "sump" system was overflowing, causing water to back up through the drain channel into the production room. The flooded floor had a sewage odor. Employees were observed tracking the standing water back and forth from the French-Fry Room and the production room.

# 4. EQUIPMENT AND UTENSILS

- a. Design and Material. Equipment and utensils should be so designed and of such material and workmanship as to be adequately cleanable, and should be properly maintained. Specifically,
  - (1) The wooden ceiling, walls, and floor bear a buildup of brown-black mold-like material.
  - (2) The bins used for storing raw potatoes are wooden and have mold-like material on the interior and exterior sides as well as the interior base.
- b. Maintenance. Equipment should be maintained so as to facilitate cleaning. Specifically, the walk-in refrigerator's forced air-cooling unit had peeling paint chips and was blowing debris near uncovered plastic bins of boiled potatoes.
- c. Seams on food-contact surfaces should be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter. Specifically, the

- convenyor belt in the processing room had uneven seams and had a dark-colored, mold-like build-up.
- d. Proper Cleaning. Your food equipment is washed using a sodium hypochlorite solution, but there is no water rinse afterwards. Proper cleaning includes a final rinse with clean water.

# 5. PROCESSES AND CONTROLS

- a. Potential for Contamination of Food and Food-Contact Surfaces: You do not take proper precautions to reduce the potential for contamination of food and food-contact surfaces with filth or other extraneous material, as evidenced by the following:
  - (1) In the walk-in refrigerator, uncovered plastic bins of boiled potatoes were stored approximately 2 ft from the forced air-cooling unit, which was blowing rust-like debris. There were also two drums overflowing with water, which an employee identified as condensate, underneath the unit.
  - (2) In the walk-in refrigerator, a fan grill covered with rust-like debris, was stored in a plastic bin designated to store boiled potatoes for cooling.
  - (3) The maintenance room, where the forklift, lubricants, tools, and other miscellaneous equipment are stored, directly opens to the hand-sorting table in the production room.
  - (4) You are not taking effective measures to protect against the inclusion of metal or other extraneous material in the raw potatoes or finished product.
- b. Temperature of Walk-In Refrigerator: You are neither performing routine temperature checks nor maintaining records of the temperature of the walk-in refrigerator. Also, there is no automatic regulating control of the temperature.

## 6. PERSONNEL

- a. Cleanliness. You do not assure that your employees conform to hygienic practices while on duty to the extent necessary to protect against contamination of food, as evidenced by the following:
  - (1) Employees did not wash their hands after eating or drinking and returning to the production line.
  - (2) No hand sanitizers are installed in the production area.
  - (3) An employee was observed driving the forklift, doing general plant maintenance and blowing his nose, but not washing his hands prior to unloading/loading finished product into delivery vans.

At the conclusion of the inspection, the insanitary practices and conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Dennis K. Linsley 'District Director

San Francisco District

Enclosure: Form FDA 483